



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,585	11/13/2000	Chawnshang Chang	920920.90045	7198

23859 7590 07/16/2003
NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 07/16/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,585

Applicant(s)

Chawnshang

Examiner

Nirmal S. Basi

Art Unit

1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 20, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1646

DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, drawn to method of screening a compound for use the treatment of androgen related disease comprising testing the compound to determine the effect of the compound on nuclear receptor transcription activity, classified in class 435, subclass 6, for example .
- II. Claims 2, drawn to method of screening a compound for use the treatment of estrogen related disease comprising testing the compound to determine the effect of the compound on nuclear receptor transcription activity, classified in class 435 subclass 6, for example .

Art Unit: 1646

- III. Claim 3, drawn to a method for modulating the sensitivity of a cell to a sex hormone comprising the step of stimulating in the cell the abundance of a nuclear receptor, classified in class 435, subclass 7.1 for example.
- IV. Claim 4, drawn to a method for modulating androgen receptor-mediated transactivation activity in cell, classified in class 435, subclass 7.1 for example.
- V. Claim 5, drawn to a method for down regulating androgen receptor-mediated transactivation activity in a cell, classified in class 435, subclass 7.2 for example.
- VI. Claim 6-8, drawn to a method for modulating estrogen receptor-mediated transactivation activity in cell, classified in class 435, subclass 7.2 for example.
- VII. Claim 9, drawn to a method for down regulating TR2, classified in class 435, subclass 7.1 for example.
- VIII. Claims 10-12, drawn to method of screening a compound for treating androgen receptor-related disease comprising exposing cells to the compound and determining the effect of the compound on orphan receptor signaling pathway in the cells,, classified in class 435, subclass 375, for example .
- IX. Claims 13-15, drawn to method of screening a compound for treating estrogen receptor-related disease comprising exposing cells to the compound and determining the effect of the compound on TR2 orphan receptor signaling pathway in the cells,, classified in class 435, subclass 375, for example .

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1646

The methods of Inventions I-IX are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-IX would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

The claims of Group I, II, III, IV, IV and VIII are drawn to the use of a multitude of orphan receptors (TR2, TR 4 and RXR receptor). The claims apply to numerous structurally and functionally different nucleic acids and their encoded polypeptides. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. The methods of use of each of the different orphan receptors are independent and distinct because no common structural or functional properties are shared. There is no description of definitive structural or functional features of the claimed Markush group. The Markush group contains no conserved regions which is critical to the structure and function of the genus claimed. The common function of the claimed genus of polynucleotides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. Accordingly, these claims are subject to restriction under U.S.C. § 121. Upon election of Groups I, II, III, IV, IV, IV and VIII, Applicants is additionally required to elect a single nucleic acid. This requirement is not to be constructed as a requirement for election of species, since each of the compounds

Art Unit: 1646

recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

An election to prosecute one of the groups listed I -IX must be made. Affirmation of this election must be made by applicant in responding to this Office action.

5 Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently
10 named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this
20 Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding
25 should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Serial Number:09/711,585

Page 6

Art Unit: 1646

Nirmal S. Basi

Art Unit 1646

July 14, 2003

5



YVONNE EYLER, PH.D

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

THE DOCUMENT(S) ACCOMPANYING THIS FACSIMILE TRANSMISSION CONTAIN(S) INFORMATION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE WHICH IS CONFIDENTIAL AND/OR LEGALLY PRIVILEGED. THIS INFORMATION IS FOR THE USE OF THE INDIVIDUAL OR FIRM NAMED ON THIS SHEET. IF YOU ARE NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, COPYING, DISTRIBUTION, OR THE TAKING OF ANY ACTION IN RELIANCE ON THE CONTENTS OF THIS INFORMATION IS STRICTLY PROHIBITED. THE DOCUMENTS SHOULD BE RETURNED TO THE PATENT AND TRADEMARK OFFICE IMMEDIATELY. IF THIS FACSIMILE IS RECEIVED IN ERROR, PLEASE NOTIFY THE ATTORNEY LISTED HEREON IMMEDIATELY.